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|---|----------------------|------------------------|-----------------------|
| TRANSMITTAL FORM (to be used for all correspondence after initial filing) | Application Number | 10/671,074 | |
| | Filing Date | September 25, 2003 | |
| | First Named Inventor | Kenneth W. Dobie | |
| | Art Unit | Not Yet Assigned | |
| | Examiner Name | Not Yet Assigned | |
| Total Number of Pages in This Submission | 7 | Attorney Docket Number | AMGN0001-101 (A-829A) |

| ENCLOSURES (check all that apply) | | |
|---|--|--|
| <input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) | <input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below): |
| Remarks | | |

| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT | |
|--|---------------------------------------|
| Firm or Individual name | David A. Sadewasser/Reg. No. P-55,587 |
| Signature | <i>David A. Sadewasser</i> |
| Date | <i>February 2, 2004</i> |

| CERTIFICATE OF MAILING | | | |
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| I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below. | | | |
| Typed or printed name | David A. Sadewasser | | |
| Signature | <i>David A. Sadewasser</i> | Date | <i>February 2, 2004</i> |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of: Kenneth W. Dobie, et al

Serial No.: 10/671,074

Group Art Unit: Not Yet Assigned

Filing Date: September 25, 2003

Examiner: Not Yet Assigned

For: MODULATION OF FORKHEAD
BOX 01A EXPRESSION

DATE OF DEPOSIT: February 2, 2004
I HEREBY CERTIFY THAT THIS PAPER IS BEING
DEPOSITED WITH THE UNITED STATES POSTAL
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David A. Sadewasser
TYPED NAME: David A. Sadewasser
REGISTRATION NO: P-55,587

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

This Information Disclosure Statement is being filed:

- ☐ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- ☒ **before** the mailing date of a first Office Action on the merits.
- ☐ **after** the mailing date of a first Office Action on the merits, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
- ☐ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);
- or**
- ☐ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
- ☐ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ **after** the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before, or simultaneously with, the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), a Petition requesting consideration of the Information Disclosure Statement and the Petition Fee of \$130.00 set forth in 37 C.F.R. § 1.17(i)(1) (see "Statement," "Petition," and "Fees" below).
- ☒ Copies of references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are enclosed.

EXCEPT THAT:

- ☐ In view of the voluminous nature of reference AG, and the likelihood that this reference is available to the Examiner, copies are not enclosed herewith.
- ☒ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.

- ☒ Copies of references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 were previously cited by or submitted to the U.S. Patent and Trademark Office in parent application Serial No. 10/260,203 filed on September 26, 2002.
- ☒ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Statement under 37 C.F.R. § 1.97(e)

- ☐ The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

Petition

- ☐ Applicant(s) hereby petitions the Assistant Commissioner to consider the references listed in this Information Disclosure Statement, on the enclosed PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449, and the examination of the above-identified patent application.

Fees

- ☒ No Fee is owed by the applicant(s).
- ☐ The Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.
- ☐ The Petition Fee of \$130.00 under 37 C.F.R. § 1.17(i)(1) is enclosed herewith.

Method of Payment of Fees

- ☐ Attached is a check in the amount of \$_____. This form is submitted in duplicate.
- ☐ Charge Deposit Account No. 50-1275 in the amount of \$_____. This form is submitted in duplicate.
- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.

☒ No fee or Statement is required under 37 C.F.R. § 1.97(b).

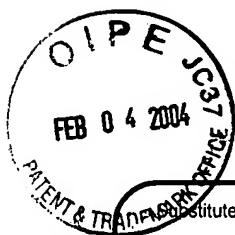
Respectfully submitted,



David A. Sadewasser
Registration No. P-55,587

Dated: February 2, 2004

COZEN O'CONNOR, P.C.
1900 Market Street, 5th Floor
Philadelphia, PA 19103-3508
(215) 665-2000 – Telephone
(215) 701-2013 - Facsimile



PTO/SB/08b(05-03)

Approved for use through 04/30/2003. OMB 0651-0031

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|---|------------------------|--------------------------|--------------------|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Complete if Known | |
| | | Application Number | 10/671,074 |
| | | Filing Date | September 25, 2003 |
| | | First Named Inventor | Kenneth W. Dobie |
| | | Group Art Unit | Not Yet Assigned |
| | | Examiner Name | Not Yet Assigned |
| Sheet 1 of 2 | Attorney Docket Number | AMGN0001-101 (A-829A) | |

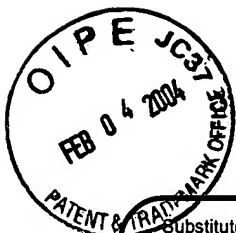
| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | |
|--|-----------------------|---|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | AA | ANDERSON, et al., "Genes, chromosomes and rhabdomyosarcoma," Genes Chromosomes Cancer (1999) 26:275-285. | |
| | AB | ANDERSON, et al., "PAX3-FKHR induces morphological change and enhances cellular proliferation and invasion in rhabdomyosarcoma," Am. J. Pathol. (2001) 159:1089-1096. | |
| | AC | ANDERSON, et al., "Embryonic expression of the tumor-associated PAX3-FKHR fusion protein interferes with the developmental functions of Pax3," Proc. Natl. Acad. Sci. USA (2001) 98:1589-1594. | |
| | AD | BENNICELLI, et al., "Mechanism for transcriptional gain of function resulting from chromosomal translocation in alveolar rhabdomyosarcoma," Proc. Natl. Acad. Sci. USA (1996) 93:5455-5459. | |
| | AE | BERNASCONI, et al., "Induction of apoptosis in rhabdomyosarcoma cells through down-regulation of PAX proteins," Proc. Natl. Acad. Sci. USA (1996) 93:13164-13169. | |
| | AF | DAVIS, et al., "Fusion genes resulting from alternative chromosomal translocations are overexpressed by gene-specific mechanisms in alveolar rhabdomyosarcoma," Proc. Natl. Acad. Sci. USA (1997) 94:8047-8051. | |
| | AG | DAVIS, et al., "Structural characterization of the FKHR gene and its rearrangement in alveolar rhabdomyosarcoma," Human Mol. Genet. (1995) 4:2355-2362. | |
| | AH | DAVIS, et al., "Fusion of PAX7 to FKHR by the variant t(1;13)(p36;q14) translocation in alveolar rhabdomyosarcoma," Cancer Res. (1994) 54:2869-2872. | |
| | AI | DEL PESO et al., "Regulation of the forkhead transcription factor FKHR, but not the PAX3-FKHR fusion protein, by the serine/threonine kinase, Akt," Oncogene (1999) 18:7328-7333. | |
| | AJ | DURHAM, et al., "FKHR binds the insulin response element in the insulin-like growth factor binding protein-1 promoter," Endocrinology (1999) 140:3140-3146. | |
| | AK | EPSTEIN, et al., "Tumor-specific PAX3-FKHR transcription factor, but not PAX3, activates the platelet-derived growth factor alpha receptor," Mol. Cell. Biol. (1998) 18:4118-4130. | |

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|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO/SB/08b(05-03)

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 2

Complete if Known

| | |
|------------------------|-----------------------|
| Application Number | 10/671,074 |
| Filing Date | September 25, 2003 |
| First Named Inventor | Kenneth W. Dobie |
| Group Art Unit | Not Yet Assigned |
| Examiner Name | Not Yet Assigned |
| Attorney Docket Number | AMGN0001-101 (A-829A) |

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|------------------------|--------------------------|---|----------------|
| | AL | GAJIWALA, et al., "Winged helix proteins," Curr. Opin. Struct. Biol. (2000) 10:110-116. | |
| | AM | GALILI, et al., "Fusion of a fork head domain gene to PAX3 in the solid tumor alveolar rhabdomyosarcoma," Nat. Genet. (1993) 5:230-235. | |
| | AN | GUO, et al., "Phosphorylation of serine 256 by protein kinase B disrupts transactivation by FKHR and mediates effects of insulinon insulin-like growth factor -binding protein-1 promoter activity through a conserved insulin response sequence," J. Biol. Chem. (1999) 274:17184-17192. | |
| | AO | MARGUE, et al., "Transcriptional modulation of the anti-apoptotic protein BCL-XL by the paired box transcription factors PAX3 and PAX3/FKHR," Oncogene (2000) 19:2921-2929. | |
| | AP | NAKAE, et al., "The forkhead transcription factor Foxo1 (FKHR) confers insulin sensitivity onto glucose-6-phosphatase expression," J. Clin. Invest. (2001) 108:1359-1367. | |
| | AQ | SCHEIDLER, et al., "The hybrid PAX3-FKHR fusion protein of alveolar rhabdomyosarcomatransforms fibroblasts in culture," Proc. Natl. Acad. Sci. USA (1996) 93:9805-9809. | |
| | AR | TANG, et al., "Negative regulation of the forkhead transcription factor by FKHR by Akt," J. Biol. Chem. (1999) 274:16741-16746. | |
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|-----------------------|--|--------------------|--|
| Examiner Signature | | Date Considered | |
|-----------------------|--|--------------------|--|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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